

REMARKS

Claims 1-127 were pending in this application. Applicants note with appreciation that the elected antibody sequences are free of the prior art. Applicants also note that the restriction requirement was made final and thus, claims 41-52, drawn to a non-elected invention, were withdrawn from consideration. In view of their withdrawal from consideration, claims 41-52 have been canceled, without prejudice to Applicants' rights to pursue the subject matter of the canceled claims in related applications. Applicants have also canceled claims 1-40 and 53-127, without prejudice to Applicants' right to pursue the subject matter of the canceled claims in related applications, and added new claims 128-203, directed to the elected subject matter. Upon entry of this Amendment, claims 128-203 will be pending. The new claims are fully supported by the specification of the present application (see, *e.g.*, page 8, line 31 to page 9, line 20; page 10, line 3 to page 11, line 2; page 16, line 12 to page 18, line 28; page 28, lines 12-16; page 34, line 32 to page 35, line 10; page 35, lines 23-35; page 36, lines 1-32; page 41, line 18 to page 42, line 4; page 47, line 27 to page 52; page 60, line 1 to page 63, line 8; page 79, lines 9-23; page 80, lines 1-31; page 86, lines 5-12; page 86, lines 22-28; page 91, lines 25-28; and page 92, lines 1-10 of the specification), and do not constitute new matter.

Entry of the foregoing amendments and consideration of these remarks are respectfully requested.

1. THE OBJECTION TO THE CLAIMS SHOULD BE WITHDRAWN

Claims 1 and 28 are objected to, respectively, for lacking a comma after the term "preventing" and for lacking the word "of" after the term "administration". Applicants have canceled claims 1 and 28, without prejudice. Accordingly, the objection to claims 1 and 28 is moot. Therefore, the objection to claims 1 and 28 cannot stand and should be withdrawn.

2. THE REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH, SHOULD BE WITHDRAWN

Claims 1-40 and 53-127 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. For the reasons detailed below, the rejections under 35 U.S.C. § 112, second paragraph, cannot stand and should be withdrawn.

The Examiner contends that the recitation of the trademark “SYNAGIS®” renders claims 66-73, 90-95, 101, 105, and 122-127 indefinite. Applicants have canceled claims 66-73, 90-95, 101, 105, and 122-127, without prejudice, and added new independent claims 135 and 136 (and claims dependent therefrom) that recite the term “palivizumab”, not “SYNAGIS®”. Accordingly, Applicants respectfully assert that the rejection of claims 66-73, 90-95, 101, 105, and 122-127 under 35 U.S.C. § 112, second paragraph, for the recitation of the trademark “SYNAGIS®” is moot.

The Examiner contends that the recitation of the term “increased *in vivo* half-lives” renders claims 86-89 and 93-111. Applicants respectfully disagree. However, in order to expedite the prosecution of the present application and without conceding to the validity of the Examiner’s rejection, claims 86-89 and 93-111 have been canceled, without prejudice. Accordingly, Applicants respectfully assert that the rejection of claims 86-89 and 93-111 under 35 U.S.C. § 112, second paragraph, for the recitation of the term “increased *in vivo* half-lives” is moot.

The Examiner contends that the recitation of the term “effective amount” renders claims 1-40 and 53-127 indefinite. In particular, the Examiner contends that the meaning of the phrase “effective amount” is unclear. Applicants respectfully disagree and assert that one of skill in the art would appreciate the meaning of the phrase “effective amount” in view of the teaching in the specification of the application regarding the phrase “effective amount” and assays for determining therapeutic effectiveness (see, *e.g.* page 1, lines 4-8 and Section 5.4). The courts have consistently held the phrase “an effective amount” to be definite where those skilled in the art would be able to determine from the written description what an effective amount is by understanding the function which is to be achieved or the use which is to be affected. See, *e.g.*, *In re Halleck*, 422 F.2d 911, 164 U.S.P.Q. 647 (CCPA 1970) and *In re Watson*, 517 F.2d 465, 186 U.S.P.Q. 11 (CCPA 1975). Accordingly, Applicants respectfully submit that one of skill would appreciate the endpoints that indicate that effectiveness has been achieved based upon the teaching in the specification of the application.

However, in order to expedite the prosecution of the present application and without conceding to the validity of the Examiner’s rejection, claims 1-40 and 53-127 have been canceled, without prejudice. New independent claims 128-136 (and claims dependent therefrom) recite a method of preventing a RSV infection or a symptom thereof comprising administering to a mammal a dose of an effective amount of a specific antibody that results in

an *effective neutralizing titer* of the antibody. Thus, the presently pending claims specify that an “effective amount” results in an “effective neutralizing titer.” The phrase “effective neutralizing titer” is defined at page 28, lines 12-16 of the specification of the application as the amount of serum present in a human that is either clinically efficacious or reduces virus by 99%, and the specification at, *e.g.*, Examples 10 and 11 describes assays for determining an effective neutralizing titer. Thus, Applicants respectfully submit that one skill in the art would understand the scope of the phrase “effective neutralizing titer.” Accordingly, Applicants respectfully assert that the rejection of claims 1-40 and 53-127 under 35 U.S.C. § 112, second paragraph, for the recitation of the term “effective amount” is moot.

In view of the foregoing, Applicants respectfully assert that the rejections under 35 U.S.C. § 112, second paragraph, cannot stand and should be withdrawn.

**3. THE REJECTION UNDER 35 U.S.C § 102
SHOULD BE WITHDRAWN**

Claims 1-4, 6-11, 13-18, 21, 23-26, 28-34 and 36-39 are rejected under 35 U.S.C. § 102(b) as being anticipated by Subramanian et al., 1998, *Ped. Infect. Dis. J.* 17:110-115 (“Subramanian”). The Examiner contends that Subramanian teaches the intravenous administration of palivizumab to infants at doses of 3, 10 and 15 mg/kg once a month, for up to five doses, and that at 3 mg/kg the serum concentration after 30 days was 6.8 mg/ml. In order to expedite the prosecution of the application and without conceding to the validity of the rejection, Applicants have canceled claims 1-4, 6-11, 13-18, 21, 23-26, 28-34 and 36-39, without prejudice, and added new claims 128-203, directed to methods of preventing a RSV infection or a symptom thereof, comprising administering an antibody having a particular amino sequence, other than the amino acid sequence of palivizumab. Thus, the presently pending claims do not recite administering palivizumab for the prevention of a RSV infection or a symptom thereof. Accordingly, Applicants respectfully assert that the rejection of claims 1-4, 6-11, 13-18, 21, 23-26, 28-34 and 36-39 under 35 U.S.C. § 102(b) is moot. Therefore, the rejection of claims 1-4, 6-11, 13-18, 21, 23-26, 28-34 and 36-39 under 35 U.S.C. § 102(b) cannot stand and should be withdrawn.

**4. THE REJECTION UNDER 35 U.S.C § 103
SHOULD BE WITHDRAWN**

Claims 53-84, 86-110, 112-120 and 122-127 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the MedImmune package insert for Synagis® (the “Package Insert”) or Subramanian in view of Lam et al., 1997, *Proc. Int’l Symp. Rel. Bioact. Mater.* 24:759-760

("Lam") and Gonzalez et al., U.S. Patent No. 6,117,980 ("Gonzalez"). As set forth in the Office Action, the Examiner contends that: (a) the Package Insert and Subramanian teach the administration of palivizumab to infants at doses of 3, 10 and 15 mg/kg; (b) Lam "discloses sustained release microencapsulation pharmaceutical formulations of recombinant humanized antibodies for patients with macular degeneration"; and (c) "Gonzalez teaches the administration of humanized anti-IL-8 monoclonal antibody or fragments thereof via known therapeutic methods, such as inhalation, injection, intramuscular and sustained release." The Examiner alleges that it would have been *prima facie* obvious to administer a sustained release formulation of palivizumab via inhalation. In order to expedite the prosecution of the application and without conceding to the validity of the rejection, Applicants have canceled claims 53-84, 86-110, 112-120 and 122-127, without prejudice, and added new claims 128-203, directed to methods of preventing a RSV infection or a symptom thereof, comprising administering an antibody having a particular amino sequence, other than the amino acid sequence of palivizumab. Thus, the presently pending claims do not recite administering palivizumab for the prevention of a RSV infection or a symptom thereof. Accordingly, Applicants respectfully assert that the rejection of claims 53-84, 86-110, 112-120 and 122-127 under 35 U.S.C. § 103(a) is moot. Therefore, the rejection of claims 53-84, 86-110, 112-120 and 122-127 under 35 U.S.C. § 103(a) cannot stand and should be withdrawn.

**5. THE DOUBLE PATENTING REJECTION
SHOULD BE WITHDRAWN**

Claims 53-65 are provisionally rejected under the judicially created doctrine of double patenting over claims 85-191 of copending U.S. application Serial No. 09/724,396. Applicants have canceled claims 53-65, without prejudice. Accordingly, Applicants respectfully assert that the rejection of claims 53-65 under the judicially created doctrine of double patenting is moot. Therefore, the rejection of claims 53-65 under the judicially created doctrine of double patenting cannot stand and should be withdrawn.

CONCLUSION

Applicants believe that the present claims meet all the requirements for patentability. Entry of the foregoing amendments and remarks into the file of the above-identified application is respectfully requested. Withdrawal of all rejections and reconsideration of the amended claims are requested. An allowance is earnestly sought.

If any issues remain, the Examiner is requested to telephone the undersigned.

Respectfully submitted,

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